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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SISSON, BRADLEY L

ART UNIT

PAPER NUMBER

1634

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24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/463,352

Examiner

Bradley L. Sisson

Applicant(s)

GOUDSMIT ET AL.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Workgroup 1630, Art Unit 1634.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montagnier et al., in view of Backus et al. (US Patent 6,001,558) and Research Genetics.

6. Montagnier et al., column 19, third paragraph, bridging to column 20, disclose primers for detecting HIV-1 and methods of doing same. At column 19, last paragraph, bridging to column 20, first two lines, Montagnier et al., teach explicitly of directing primers to conserved regions and specifically teaches that one such region of conserved sequences is found in the long terminal repeat, or LTR. It is noted that the LTR is the very region from which applicant has selected the instantly claimed primers/probes; see the response of 26 December 2000, page 7, lines 13-15, wherein is stated:

The primers of the present invention are not from the GAG region, but instead are from the long terminal repeat (LTR) of HIV-1."

It is abundantly clear that Montagnier et al., are directing the public to this very region for the selection of primers and probes. Furthermore, they provide motivation in selecting sequences that allow for the detection of multiple isolates when they teach that the LTR is "highly conserved."

7. Montagnier et al., column 20, second full paragraph, states that by using PCR, which they consider to be more sensitive, one would be able to eliminate viral-isolation assays.

8. While Montagnier et al., do teach of conducting PCR on the LTR region of HIV, they do not teach explicitly of applicant's sequences.

9. Backus et al., disclose at column 6, first paragraph, that primers can range in size or length from 12 to 60 nucleotides and that a preferable range is from 16 to 40 nucleotides and that a more preferable range is from 18 to 35 nucleotides. It is noted that applicant's SEQ ID NO: 1 comprises 18 nucleotides; SEQ ID NO: 2 comprises 20 nucleotides; SEQ ID NO: 4 and 5 comprises 20 nucleotides each; and SEQ ID NO: 12 comprises 30 nucleotides.

10. As seen in column 11, oligonucleotides corresponding to SEQ ID NO: 2, 4, and 24 comprise the nucleotide sequence as found in applicants oligonucleotides represented by SEQ ID NO: 1, 2, 4, 5.

11. Research Genetics, through their advertisement, disclose for sale software that allows the ordinary artisan to set parameters whereby the software will automatically screen all possible sequence comparisons and provide a listing of those primers that meet the established criteria. As seen in the publication, such parameters to be employed in the selection of primer and probe sequences include desired specificity, length, GC content, secondary structure characteristics, etc.

12. It would have been obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to have used the software of Research Genetics with the teachings of Backus et al., and Montagnier et al., so to select primers and probes from the LTR region of HIV-1 where such sequences are identified through the use of the commercially available sequence screening software. As shown above, Backus et al., disclose not only the sequences but directs the public to preferred sizes of primers. It is noted with particularity that the sizes of primers disclosed by Backus et al., corresponds to that claimed instantly. And with the public being armed with the sequences, preferred size ranges and software that will perform the

necessary calculations and produce nucleotide sequences that meet such criteria, the selection of primer sequences that have such features would have been profoundly obvious. And given the art-recognized sensitivity of PCR and the interests that abounds in HIV-related diagnostics, the ordinary artisan would have been highly motivated as well. Additionally, said ordinary artisan would have been motivated to have configured the primer pair(s) in a kit format as such would have been an obvious commercial expedience, requiring little if any additional research and development.

13. Acknowledgement is made of applicant's argument where it is asserted that Bacus et al., teaches performing amplification with two sets of primers. This argument has been fully considered and has not been found persuasive. It is first noted that claims 1-4, 8 and 9 are not drawn to a method of any kind, but rather, are drawn to a product- PCR primers and a kit that comprises same. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained as applicant is arguing limitations not found in the claims.

14. In so far as applicant claims a method of amplification, it is noted that the method claims do not exclude the use of additional primer pairs. Support for this position is based in part on the use of the term "comprising," which allows for the inclusion of additional method steps and reagents, even in significant amounts. Accordingly, the method claims are considered, for purposes of examination, of encompassing the use of single primer pair as well as an unlimited number of primer pairs. Even if the claims were to be limited to where but a single pair of primers were to be used, it is noted that Backus et al., columns 11-12 teach explicitly of performing amplification with single sets of primers, including performing amplification with primers 24/2 and 2/4; see Table 1.

Declaration under 37 CFR 1.132

15. Acknowledgement is made of applicant's having filed a declaration by one Bob van Gemen, Ph.D.; received 20 September 2002. It is noted with particularity that declarant is a former employee of assignee and continues to "serve the Company." Accordingly, the remarks are considered to be those of one who could well hold a vested interest in the proceedings before the US Patent & Trademark Office and do not necessarily represent the opinion of a disinterested third party.

16. While declarant has presented evidence that their primers yielded results that are alleged to be more sensitive than obtainable by other commercially available primers, such a showing has not been found to be dispositive of the foregoing rejection. It is noted that the rejection has not been made with primers being from any commercially available source, but rather, the rejection has been made over prior art that explicitly teaches primers that comprise applicant's SEQ ID NO: 1, 3, 5, and 12 and which also teaches primers that have a length encompassed by the present claims. Indeed, SEQ ID NO: 4 of Backus et al., which is but 23 nucleotides long (the claims allow for primers of 26 nucleotide in length), fairly anticipates applicant's SQ ID NO: 1 and 3 as SEQ ID NO: 4 corresponds to 18 nucleotides of SEQ ID NO: 1 and 15 nucleotides of SEQ ID NO: 3.

17. Accordingly, he declaration of Gemen has not been found present convincing evidence of how knowledge of and use of the claimed sequences does not render obvious same, especially when the prior art also teaches explicitly of limiting the size of the primers to corresponding values.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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22. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
November 24, 2002